IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Zeldis *et al.*	Confirmation No.:	7262
Serial No.:	09/853,617	Art Unit:	1623
Filed:	May 14, 2001	Examiner:	Dr. Patrick T. Lewis
For:	COMPOSITIONS AND METHODS FOR THE TREATMENT OF CANCER	Attorney Docket No: CAM:	501872-999021 9516-022-999

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(b)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants respectfully request reconsideration of the Determination of Patent Term Adjustment under 35 U.S.C. §154(b) mailed May 13, 2008 ("Determination") in connection with the above-referenced application. It is alleged in the Determination that the Patent Term Adjustment is 47 days. Applicants respectfully disagree and submit that the correct Patent Term Adjustment is 442 days.

Applicants respectfully invite the Office's attention to the Patent Term Adjustment History[1] ("History") obtained from the Patent Application Information Retrieval ("PAIR") of the United States Patent and Trademark Office ("USPTO") website. According to the History, a Non-Final Rejection was mailed May 19, 2003. However, contrary to what is described in the History, a Response to this Non-Final Rejection was not mailed on March 12, 2004. Rather, a Response was timely filed on August 19, 2003, *i.e.*, within three-months of the date of mailing of the Non-Final Rejection of May 19, 2003. This is evidenced by: (1) a copy of the Response as filed[2], which is dated August 19, 2003; and (2) a copy of the Express Mail Receipt submitted concurrently with the Response[3], which bears a USPTO stamp having the date August 19, 2003. The Express Mail receipt is also indexed on PAIR

[1] Attached hereto as Exhibit A.
[2] Attached hereto as Exhibit B. The Response is also indexed in the "Image File Wrapper" on PAIR.
[3] Attached hereto as Exhibit C.

under the "Image File Wrapper" as a "Miscellaneous Incoming Letter" for the date of August 19, 2003.

It appears that a second copy of the Response filed August 19, 2003 was faxed to the USPTO on March 12, 2004. (*See, e.g.*, Exhibit D[4]). In this regard, Applicants respectfully submit that the Office has mistakenly considered March 12, 2004, rather than the correct date of August 19, 2003, to be the filing date of the Response. Moreover, the Office has improperly deducted 206 days resulting from this error.

Following the Response filed August 19, 2003, a subsequent Final Rejection was not mailed from by the USPTO until April 20, 2005. Under 37 U.S.C. §1.703(a)(2), the patent term adjustment is "[t]he number of days...in the period beginning on the day after the date that is four months after the date a reply in compliance with §1.111 was filed and ending on the date of mailing of...an action under 35 U.S.C. 132...." Since Applicants' Response was filed August 19, 2003, and since the subsequent Final Rejection was not mailed until April 20, 2005, the Patent Term Adjustment for the delay in mailing the Final Rejection is 518 days, rather than the 282 days indicated in the History. In other words, 236 days should be added to the Patent Term Adjustment. Thus, taking into account the 206 days improperly deducted above, the total correct Patent Term Adjustment for the above-referenced application is 442 days.

A fee of $200.00 is believed due for the submission of this paper under 37 C.F.R. §1.18(e) and 37 C.F.R. § 1.705(b)(1), which will be paid via EFS Web. However, if any additional fees are due, the Director is authorized to charge them to Deposit Account No. 50-3013.

Respectfully submitted,

Date: August 13, 2008

Hoon Choi Ltd. Reg. No.: L0209
for: Anthony M. Insogna Reg. No.:35,203
JONES DAY
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(858) 314-1200

[4] A copy is also indexed as a "Transmittal to TC" for the date of March 12, 2004 in the "Index File Wrapper" of PAIR.

Exhibit A

09/853,617	COMPOSITIONS AND METHODS FOR THE TREATMENT OF CANCER	08-13-2008::19:29:30

Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 09/853,617

Filing or 371(c) Date:	05-14-2001	USPTO Delay (PTO) Delay (days):	424
Issue Date of Patent:	-	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	377
Post-Issue Petitions (days):	+0	Total PTA (days):	47
USPTO Adjustment(days):	+0	Explanation Of Calculations	

Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
05-13-2008	Mail Notice of Allowance		
05-12-2008	Document Verification		
05-07-2008	Notice of Allowance Data Verification Completed		
04-03-2008	Date Forwarded to Examiner		
04-03-2008	Date Forwarded to Examiner		
03-25-2008	Request for Continued Examination (RCE)		26
04-03-2008	DISPOSAL FOR A RCE/CPA/129 (express abandonment if CPA)		↑
03-25-2008	Request for Extension of Time - Granted		↑
03-25-2008	Workflow - Request for RCE - Begin		↑
11-28-2007	Mail Final Rejection (PTOL - 326)		↑
11-26-2007	Final Rejection		
09-10-2007	Miscellaneous Incoming Letter		
09-19-2007	Date Forwarded to Examiner		
09-07-2007	Response after Non-Final Action		
06-14-2007	Mail Non-Final Rejection		
06-11-2007	Non-Final Rejection		
03-20-2007	Date Forwarded to Examiner		
03-20-2007	Date Forwarded to Examiner		
03-08-2007	Request for Continued Examination (RCE)		
03-20-2007	DISPOSAL FOR A RCE/CPA/129 (express abandonment if CPA)		
03-08-2007	Request for Extension of Time - Granted		
03-08-2007	Workflow - Request for RCE - Begin		
09-22-2006	Mail Advisory Action (PTOL - 303)		
09-18-2006	Advisory Action (PTOL-303)		
08-21-2006	Information Disclosure Statement considered		
06-29-2006	Information Disclosure Statement considered		
08-21-2006	Information Disclosure Statement (IDS) Filed		
08-21-2006	Information Disclosure Statement (IDS) Filed		
08-21-2006	Notice of Appeal Filed		62
08-28-2006	Date Forwarded to Examiner		↑

08-21-2006	Amendment after Final Rejection		↑
08-21-2006	Request for Extension of Time - Granted		↑
06-29-2006	Information Disclosure Statement (IDS) Filed		↑
06-29-2006	Information Disclosure Statement (IDS) Filed		↑
03-20-2006	Mail Final Rejection (PTOL - 326)		↑
03-16-2006	Final Rejection		
01-24-2006	Date Forwarded to Examiner		
01-17-2006	Response after Non-Final Action		
11-17-2005	Mail Non-Final Rejection		
11-14-2005	Non-Final Rejection		
09-29-2005	Date Forwarded to Examiner		
09-29-2005	Date Forwarded to Examiner		
09-20-2005	Request for Continued Examination (RCE)		62
09-29-2005	DISPOSAL FOR A RCE/CPA/129 (express abandonment if CPA)		↑
09-23-2005	IFW TSS Processing by Tech Center Complete		↑
09-20-2005	Workflow - Request for RCE - Begin		↑
07-26-2005	Mail Advisory Action (PTOL - 303)		↑
07-25-2005	Advisory Action (PTOL-303)		↑
07-05-2005	Date Forwarded to Examiner		↑
06-24-2005	Amendment after Final Rejection		↑
04-20-2005	Mail Final Rejection (PTOL - 326)	282	
04-18-2005	Final Rejection	↑	
02-10-2005	Date Forwarded to Examiner	↑	
03-12-2004	Response after Non-Final Action		206
05-19-2003	Mail Non-Final Rejection		↑
05-17-2003	Non-Final Rejection		
03-21-2003	Information Disclosure Statement (IDS) Filed		21
03-21-2003	Information Disclosure Statement (IDS) Filed		
03-11-2003	Date Forwarded to Examiner		↑
02-28-2003	Response to Election / Restriction Filed		↑
02-28-2003	Request for Extension of Time - Granted		
12-03-2002	Mail Restriction Requirement	142	
12-02-2002	Requirement for Restriction / Election	↑	
09-18-2002	Case Docketed to Examiner in GAU	↑	
02-08-2002	Information Disclosure Statement (IDS) Filed	↑	
02-08-2002	Information Disclosure Statement (IDS) Filed	↑	
08-02-2002	Information Disclosure Statement (IDS) Filed	↑	
08-02-2002	Information Disclosure Statement (IDS) Filed	↑	
01-18-2002	Case Docketed to Examiner in GAU	↑	
10-22-2001	Application Dispatched from OIPE	↑	
10-22-2001	Application Is Now Complete	↑	

07-11-2001	Notice Mailed--Application Incomplete--Filing Date Assigned	
07-11-2001	Correspondence Address Change	
05-18-2001	IFW Scan & PACR Auto Security Review	
05-14-2001	Initial Exam Team nn	

Close Window

Exhibit B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: ZELDIS et al.

Application No.: 09/853,617 **Group Art Unit:** 1623

Filed: May 14, 2001 **Examiner:** P. Lewis

For: COMPOSITIONS AND METHODS FOR THE TREATMENT OF CANCER **Attorney Docket No.:** 9516-022

RESPONSE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action dated May 19, 2003, Applicants submit the following amendments and remarks for entry into the record and consideration by the Examiner.

Amendments to the claims are reflected in the listing of claims that begins on page 2 of this paper.

Remarks begin on page 4 of this paper.

Amendments to the Claims

The following listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Original) A method of treating primary cancer which comprises administering to a patient in need of such treatment a therapeutically effective amount of a topoisomerase inhibitor, or a pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, and a therapeutically effective amount of thalidomide, or a pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof.

2. (Original) A method of treating metastatic cancer which comprises administering to a patient in need of such treatment a therapeutically effective amount of a topoisomerase inhibitor, or a pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, and a therapeutically effective amount of thalidomide, or a pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof.

3. (Original) The method of claim 1 or 2 wherein the cancer is cancer of the head, neck, eye, mouth, throat, esophagus, chest, bone, lung, colon, rectum, stomach, prostate, breast, ovaries, kidney, liver, pancreas, and brain.

4. (Original) The method of claim 3 wherein the cancer is colon or rectal cancer.

5. (Currently Amended) The method of claim 1 or 2 wherein the topoisomerase inhibitor is selected from the group consisting of camptothecin, ~~irinotecan~~ irinotecan, SN-38, topotecan, 9-aminocamptothecin, GG-211, DX-8951f, saintopin, UCE6, UCE1022, TAN-1518A, TAN-1518B, KT6006, KT6528, ED-110, NB-506, ED-110, NB-506, rebeccamycin, bulgarein, Hoescht dye 33342, Hoechst dye 33258, nitidine, fagaronine, epiberberine, coralyne, beta-lapachone, BC-4-1, IST-622, rubitecan, pyrazoloacridine, XR-5000, and pharmaceutically acceptable prodrugs, salts, solvates, clathrates, hydrates, and metabolites thereof.

6. (Original) The method of claim 1 wherein the topoisomerase inhibitor is not irinotecan.

7. (Original) The method of claim 5 wherein the topoisomerase inhibitor is irinotecan or SN-38.

8. (Original) The method of claim 7 wherein the irinotecan or SN-38, or pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 1 to about 1000 mg/m^2, and the thalidomide, or pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 1 to about 2000 mg.

9. (Original) The method of claim 8 wherein the irinotecan or SN-38, or pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 25 to about 750 mg/m^2, and the thalidomide, or pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 50 to about 1000 mg.

10. (Original) The method of claim 9 wherein the irinotecan or SN-38, or pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 50 to about 500 mg/m^2, and the thalidomide, or pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 100 to about 750 mg.

11. (Original) The method of claim 10 wherein the irinotecan or SN-38, or pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 100 to about 350 mg/m^2, and the thalidomide, or pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 200 to about 500 mg.

Claims 12-60. Canceled without prejudice.

Remarks

Claims 1-11 are now pending in this application. Claims 12-60 are canceled without prejudice to Applicants' rights to pursue the subject matter thereof in one or more divisional, continuation, or continuation-in-part applications. Claim 5 is amended to correct a typographical error. No new matter has been introduced.

The Rejection Under 35 U.S.C. § 112, ¶ 1, Should Be Withdrawn

On pages 3-5 of the Office Action, claims 1-11 are rejected under 35 U.S.C. § 112, ¶ 1, as allegedly failing to comply with the written description requirement. In sum, it is alleged that "the support in the specification is not adequate for the claim to the treatment of any primary or metastatic cancer comprising administering ... any topoisomerase inhibitor ..." Office Action, pages 3-4. Applicants respectfully traverse this rejection.

As the Examiner is well aware, the essential question in a written description requirement is whether "the description clearly allow[s] persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 108, 1012 (Fed. Cir. 1989). While a question as to whether a specification provides an adequate written description may arise in the context of an original claim which is not described sufficiently, there is a strong presumption that an adequate written description is present in the specification as filed. *Manual of Patent Examining Procedure* ("MPEP") § 2163.03 (emphasis added). Accordingly, the examiner has the initial burden of presenting by a preponderance of the evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. MPEP § 2163.04 (citing *In re Wertheim*, 521 F.2d 257, 263 (C.C.P.A. 1976)). A general allegation of "unpredictability in the art" is not a sufficient reason to support a rejection for lack of adequate written description. MPEP § 2163.04.

As the Examiner correctly recognized, the treatment of colorectal cancer by administering thalidomide and irinotecan is successfully demonstrated in this application at pages 31-32 of the specification. Detailed procedures of treating various cancers by administering thalidomide with other topoisomerase inhibitors are also described, for example, at pages 32-35 of the specification. Furthermore, it was well-known in the art at the time of this invention that various topoisomerase inhibitors are effective in treating various types of cancers, albeit with certain adverse

effects that could limit the amount or dose of the topoisomerase inhibitor that can be administered to patients. Therefore, Applicants respectfully submit that the claims 1-11 are adequately supported by the specification and the knowledge that was possessed by one of ordinary skill in the art. Applicants further submit that the Examiner has not met his initial burden of establishing *prima facie* case of lack of written description, as an allegation of "unpredictability in the art" is not sufficient to support such a rejection. MPEP § 2163.04.

For the foregoing reasons, Applicants respectfully request that the rejection under 35 U.S.C. § 112, ¶ 1, be withdrawn.

The Rejection Under 35 U.S.C. § 112, ¶ 2, Should Be Withdrawn

On pages 5-6 of the Office Action, claims 5 and 7-11 are rejected under 35 U.S.C. § 112, ¶ 2, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Claims 5 and 7-11 are first rejected because alphanumeric terms, such as SN-38 and GG-211, allegedly have not been adequately defined in the specification or claims. Applicants respectfully traverse this rejection.

The alphanumeric terms used in the claims are the names of topoisomerase inhibitors that are commonly used and recognized by those of ordinary skill in the art. For example, SN-38 is chemically named as 7-ethyl-10-hydroxycamptothecin (*Cancer Chemotherapy and Biotherapy: Principles and Practice*, 3rd Ed. (2001) at page 581); GG-211, also known as GI 147211, is 7-(4-methylpiperazinomethylene)-10,11-ethylenedioxy-20(S)-camptothecin (Emerson *et al.*, *Cancer Res.* 55(3): 603-609 (1995)); UCE6 is 1,3,8,10,11-pentahydroxy-2-methyl-10-(2-oxo-4-hydroxypentyl)naphtahcene-5,12-dione (Fujii *et al*, *J. Antobiot.* (Tokyo) 50(6): 490-495 (1997)); NB-506 is 6-N-formylamino-12,13-dihydro-1,11-dihydroxy-13-(β-D-glucopyranosil)-5H-indolo[2,3-a]pyrrolo[3,4-c]carbazole-5,7(6H)-dione (Takenaga *et al.*, *Drug Metab. Dispos.* 27(2): 205-212 (1999)); IST-622 is 6-O-(3-ethoxypropionyl)-3',4'-O-exo-benzylidenechartreusin (Tashiro *et al.*, *Cancer Chemother. Pharmacol.* 34(4): 287-292 (1994)); and XR-5000, also known as DACA, is N-[2-(dimethylamino)ethyl]acridine-4-carboxamide (*Cancer Chemotherapy and Biotherapy: Principles and Practice*, 3rd Ed. (2001) at page 579). The other alphanumeric terms recited by the claims also have unambiguous meanings known by those of ordinary skill in the art. For this reason, Applicants respectfully

submit that claims 5 and 7-11 are not indefinite. MPEP § 2173.05(t) (citing *Martin v. Johnson*, 454 F.2d 746 (C.C.P.A. 1972) ("Chemical compounds may be claimed by a name that adequately describes the material to one skilled in the art.")).

Claims 8-11 are next rejected as allegedly indefinite because the amount of irinotecan or SN-38 recited in the claims are expressed in a concentration range. The concentration unit used in the claims (*i.e.*, mg/m^2) means the amount in mg used per m^2 of the patient's body area. This unit is widely used in the pharmaceutical industry, especially in connection with the treatment of cancer using parenterally delivered drugs, as it is important to determine the appropriate amount to be used according to the size of the patient in treating cancers. *See, e.g., Physician's Desk Reference*, 54th Ed., page 2412-2418 (2000), which was submitted as Document BK in the Information Disclosure Statement filed February 8, 2002. For this reason, Applicants respectfully submit that the pending claims are not indefinite, and the rejection under 35 U.S.C. § 112, ¶ 2, should be withdrawn.

The Rejection Under 35 U.S.C. § 103 Should Be Withdrawn

On pages 6-9 of the Office Action, claims 1-11 are rejected as allegedly obvious over Marx *et al., Proc. Am. Soc. Clin. Oncology* 18: 454a (1999) ("Marx"), in view of Pitot *et al., Journal of Clinical Oncology* 15(8): 2910-2919 (1997) ("Pitot") and U.S. Patent No. 5,622,959 to Priel *et al.* ("the '959 patent"). In particular, it is alleged that because Marx discloses an antiangiogenic effect of thalidomide and Pitot and the '959 patent disclose antitumor activities of CPT-11 and CPT, respectively, the claimed invention is obvious. Applicants respectfully traverse this rejection for the following reasons.

As the Examiner is aware, three basic criteria must be met in order to establish a case of *prima facie* obviousness: first, there must have been a motivation to combine the cited references at the time the invention was made; second, the alleged prior art must disclose or suggest all of the limitations of the claims alleged to be obvious; and third, there must have been at the time of the invention a reasonable expectation of success. MPEP §2142. Furthermore, hindsight cannot be used to reject a claim as obvious. MPEP § 2141.01. Consequently, when determining whether or not a claimed invention is obvious, one must cast her "mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field." *In re*

Dembiczak, 175 F.3d 994, 999 (Fed.Cir. 1999) (reversing a determination that several claims were obvious over a combination of references that disclosed all of their limitations, but which did not provide a motivation to combine those limitations). Applicants respectfully submit that these criteria are not met by the combination of Marx, Pitot, and the '959 patent.

The Examiner, citing *Ex parte Quadranti*, 25 U.S.P.Q.2d 1071 (Bd. Pat. Appl. & Inter. 1992), alleges that the co-administration of two components, each of which is recognized as having anticancer activity, would have been obvious "in the absence of some proof of a secondary nature or some specific limitations which would tip the scale of patentability in favor of the claimed invention." Office Action at page 9. Applicants respectfully submit that such proof can be found in the application as filed.

As indicated in the specification, this invention is based, in part, on the ability of thalidomide to: (1) treat cancer; (2) improve the efficacy of other chemotherapeutic or radiation therapies for cancer; or (3) lessen the severity of certain dose-limiting toxicities of other anticancer drugs. The specification, page 11, line 38 - page 12, line 3. Thus, when thalidomide is co-administered with irinotecan to patients with metastatic colorectal cancer, a remarkable absence of gastrointestinal toxicity typically associated with irinotecan is observed. *Id.* at page 31, line 24 - page 32, line 21. None of the cited references disclose or even suggest this remarkable effect.

In addition, thalidomide was not an approved anticancer agent at the time of this invention, while numerous other agents known to be effective in treating cancer were. As such, these references would not have provided the necessary motivation to combine thalidomide with a topoisomerase inhibitor because one of ordinary skill in the art would have been likely to combine other known anticancer agents first with topoisomerase inhibitors. Thus, Applicants respectfully submit that the rejection under 35 U.S.C. § 103 could only be made with the aid of an impermissible hindsight. *Dembiczak*, 175 F.3d at 999. Similarly, the cited art certainly would not have provided any suggestion that the claimed invention would be successful. For these reasons, Applicants respectfully request that the rejection under 35 U.S.C. § 103 be withdrawn.

Conclusion

For the foregoing reasons, Applicants respectfully submit that claims 1-11 are allowable. No fee is believed due for this submission. However, should any fees be due for this submission or to avoid abandonment of the application, please charge such fees to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Date August 17, 2003

Respectfully submitted,

45,479
Max Bachraeh (Reg. No.)

PENNIE & EDMONDS LLP
1667 K Street, N.W.
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(202) 496-4400

For: Anthony M. Insogna (Reg. No. 35,203)
PENNIE & EDMONDS LLP
1155 Avenue of the Americas
New York, NY 10036
(212) 790-9090

Exhibit C

Ex
Dat
Ser.
Inv
For

HAND CARRY
Date Mailed August 19, 2003
Serial No. 09/853,617 Filed May 14, 2001
Inventor ZELDIS et al.
For COMPOSITIONS AND METHODS FOR THE TREATMENT OF CANCER

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☐ Affidavit/Declaration
☒ Amendment
☐ Application pages
☐ Claims Drawing Sheet
☐ Appeal, Notice of
☐ Assignment
☐ Brief (in Triplicate)
☐ Declaration of Inventors
☐ Design Application
☐ Disclaimer
☐ Disclaimer
☐ Disclosure Statement ☐Form PTO-1449
☐w.refs. ☐ w/o refs.
☐ Drawings, Formal
Sheets Figures
Other:

File no.: 9516-022-999

☐ Fee Address Indication Form
☐ Fee Calculation
☐ Issue Fee Transmittal
☐ Letter
☐ Oral Hearing Request/Confirm
☐ Petition to Extend Time
☐ Petition Under 37 C.F.R.
☐ Power of Attorney
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AUG 19 2003
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Exhibit D

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March 12, 2004

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Examiner Patrick Lewis	571-273-0655	

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Re: U.S. Patent Application No. 09/853,617

Message: Attached is a copy of the postcard receipt and Response.

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